

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

OREXO AB,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC. and
MYLAN INC.,

Defendants.

Civil Action No. 3:11-cv-3788-FLW-LHG

Hon. Freda L. Wolfson, U.S.D.J.

Hon. Lois H. Goodman, U.S.M.J.

Document Filed Electronically

**DEFENDANTS' PROPOSED FINDINGS OF
FACT AND CONCLUSIONS OF LAW IN FURTHER
SUPPORT OF PLAINTIFF'S MOTION TO SEAL (ECF NO. 124)**

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INTRODUCTION

Pursuant to Local Civil Rule 5.3(c), Defendants/Counterclaim-Plaintiffs Mylan Laboratories Limited and Mylan Inc. (collectively, “Mylan”) hereby submit Proposed Findings of Fact and Conclusions of Law in further support of Plaintiff Orexo AB’s Motion to Seal (ECF No. 124). Local Civil Rule 5.3(c) places the burden of proof on the moving party as to why a motion to seal or otherwise restrict public access should be granted. Specifically, it requires a showing of:

- (1) the nature of the materials or proceedings at issue;
- (2) the legitimate private or public interest which warrants the relief sought;
- (3) the clearly defined and serious injury that would result if the relief sought is not granted; and
- (4) why a less restrictive alternative to the relief sought is not available.

Orexo and Mylan seek to seal the following documents Orexo electronically filed in connection with its Motion for the Issuance of a Letter of Request to the Central Authority of India for the Testimony from Subash Chandra Mohanta and P. Kurali Krishna:

- Orexo AB’s Memorandum of Law in Support of Plaintiff Memorandum of Law in Support of Plaintiff Orexo AB’s Motion for the Issuance of a Letter of Request to the Central Authority of India for Testimony from Subash Chandra Mohanta and P. Murali Krishna (ECF No. 123) (“Orexo’s Brief”) at page 4, line 11 to page 5, line 2 between the words “Misters Mohanta and Krishna” and “Mylan’s ANDA Products”;
- Orexo’s Brief at page 6, lines 6–17 between the words “Mr. Mohanta” and “Mylan’s ANDA Products”;
- Orexo’s Brief at page 10, lines 4–7 between the words “Specifically” and “discoverable evidence”;
- Orexo’s Brief at page 11, lines 7–14 between the words “The two” and “observed and evaluated;” and
- Exhibits A, C, D, E, F.

Set forth below are the findings of fact and conclusions of law addressing each of the elements of Local Civil Rule 5.3(c). These findings of fact and conclusions of law support the

granting of Orexo's Motion to Seal, as further supplemented by Mylan, the Confidential Documents identified herein.

DISCUSSION

I. THE NATURE OF THE MATERIALS OR PROCEEDINGS AT ISSUE

A. Findings of Fact

1.) The Confidential Documents contain and/or reflect information contained in or derived from Mylan's Abbreviated New Drug Applications ("ANDA") and confidential manufacturing, formulation, and research and development information. (*See* Declaration of Constantine Koutsoubas, filed herewith ("Koutsoubas Decl.") at ¶ 8.) Some of the Confidential documents contain sensitive personal information of the third party witnesses that are the subject of Orexo's underlying motion. (*Id.*) The Confidential Documents reflect information that is presently confidential and unavailable to the public. (*Id.*)

B. Conclusions of Law

2.) There exists in civil cases a common law public right of access to judicial proceedings and records. *In re Cendant Corp.*, 260 F.3d 183, 192 (3d Cir. 2001) (citing *Littlejohn v. BIC Com.*, 851 F.2d 673, 677–78 (3d Cir. 1988)). The party seeking to seal any part of a judicial record bears the burden of demonstrating that "the material is the kind of information that courts will protect." *Miller v. Indiana Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994) (quoting *Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1071 (3d Cir. 1984)).

3.) This Court has the power to seal where confidential information may be disclosed to the public. Fed. R. Civ. P. 26(c)(1)(G) allows the court to protect materials containing "trade secret[s] or other confidential research, development, or commercial information[.]" upon motion by a party, to prevent harm to a litigant's competitive standing in the marketplace. *See Zenith Radio Com. v. Matsushita Elec. Indus. Co., Ltd.*, 529 F. Supp. 866, 889–91 (E.D. Pa. 1981).

4.) This Court must also seal sensitive personal information of individuals pursuant to L. Civ. R. 5.2 ¶ 17.

II. THE LEGITIMATE PRIVATE OR PUBLIC INTEREST WHICH WARRANTS THE RELIEF SOUGHT

A. Findings of Fact

5.) The Confidential Documents sought to be sealed contain information that was designated as confidential and proprietary under the Discovery Confidentiality Order, entered by this Court on March 26, 2012 (ECF No. 47) that presently governs the instant action. (Koutsoubas Decl., ¶ 8.) It also contains sensitive personal information of the third party witnesses that are the subject of Orexo's motion. (*Id.*)

6.) Counsel for Mylan has submitted a Declaration stating that Mylan has an interest in not publicly disclosing this information, has not publicly disclosed this information, and, in the case of some of the information, relies on such information to gain a competitive advantage in the pharmaceutical industry. (*See* Declaration of Constantine Koutsoubas, filed herewith ("Koutsoubas Decl.")).

7.) Commercially sensitive and proprietary information, such as non-public information related to Mylan's ANDA, from which competitors could identify Mylan's commercial interests embodies content which, if disclosed, might (and likely would) harm Mylan's competitive standing. (Koutsoubas Decl. ¶ 9.)

8.) Personal sensitive information of the third party witnesses that are the subject of the Orexo's underlying motion should be redacted as a matter of course pursuant to Local Civil Rule 5.2 ¶ 17.

9.) Orexo and Mylan—private parties—are in a patent dispute. Mylan has a legitimate interest in ensuring that its confidential and proprietary non-public information remain undisclosed. (Koutsoubas Decl. ¶¶ 8–9.) If this information were to become publicly available, then Mylan's competitors could potentially (and likely would) use that information in the highly competitive pharmaceutical product marketplace. (*Id.* at ¶ 9.)

B. Conclusions of Law

10.) The presumption of public access is not absolute and may be rebutted. *Republic of the Philippines v. Westinghouse Elec. Corp.*, 949 F.2d 653, 662 (3d Cir. 1991). “Every court has supervisory power over its own records and files, and access has been denied where court files might have become a vehicle for improper purposes.” *Littlejohn*, 851 F.2d at 678 (quoting *Nixon v. Warner Commc’ns, Inc.*, 435 U.S. 589, 598 (1978)).

11.) Courts may deny access to and seal a document when it encompasses business information that might harm a litigant’s competitive standing. *See Littlejohn*, 851 F.2d at 678 (citations omitted).

12.) Courts should restrict access to personal sensitive information of individuals. L. Civ. R. 5.2 ¶ 17.

13.) The District of New Jersey has held that the inclusion of trade secrets and other confidential information in documents warrant the sealing of such documents. “A well-settled exception to the right of access is the ‘protection of a party’s interest in confidential commercial information, such as a trade secret, where there is a sufficient threat of irreparable harm.’” *In re Gabapentin Patent Litig.*, 312 F. Supp. 2d 653, 664 (D.N.J. 2004) (citation omitted). “The presence of trade secrets or other confidential information weighs against public access and, accordingly, documents containing such information may be protected from disclosure.” *Id.* (citations omitted).

14.) Information included in an ANDA often consists of trade secrets, and federal law requires such information to remain confidential. *See id.* at 667 n.7 (citing 21 C.F.R. § 314.430(b)-(d)). As such, a party’s confidential processes, chemical formulas and specifications, and research information should be sealed. *Gabapentin*, 312 F. Supp. 2d at 667–68.

III. THE CLEARLY DEFINED AND SERIOUS INJURY THAT WOULD RESULT IF THE RELIEF SOUGHT IS NOT GRANTED

A. Findings of Fact

15.) In light of its reference to, and disclosure of, non-public business information that is otherwise unavailable to third parties, the public disclosure of the Confidential Documents identified above poses a substantial risk of harm to Mylan's legitimate proprietary interests and competitive position. (Koutsoubas Decl., ¶ 9)

16.) Disclosure of specific information related to Mylan's business practices would permit competitors to develop business strategies to duplicate, undercut, or otherwise counter Mylan's commercial performance. (*Id.*)

17.) Competitors would improperly benefit from the disclosure of Mylan's non-public business information and would likely use the confidential information to enhance their market or negotiation positions.

B. Conclusions of Law

18.) This Court has discretion to balance the factors for and against access to court documents. *See Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 781 (3d Cir. 1994).

19.) Protection of a party's interest in confidential commercial information, such as a trade secret, is a sufficient threat of irreparable harm, and is clearly defined as a serious injury. *See Publiker*, 733 F.2d at 1071.

20.) The public's interest in having access to the specific information presented in the Confidential Documents does not outweigh the competitive harms, which Mylan likely would sustain if the information were disclosed.

IV. A LESS RESTRICTIVE ALTERNATIVE TO THE RELIEF SOUGHT IS NOT AVAILABLE

A. Findings of Fact

21.) Moreover, Mylan's request to seal the Confidential Documents is narrowly tailored to restrict access only to confidential and proprietary information concerning the products that are the subject of Mylan's ANDA.

22.) The disclosure of this confidential, proprietary information would pose a financial and competitive risk to Mylan. The only way to protect Mylan's confidential interests is to seal the identified documents.

B. Conclusions of Law

23.) Under Local Civil Rule 5.3(c)(2), a party seeking to seal documents must meet the fourth prong that a no less restrictive alternative to the relief sought is available. See *Securimetrics, Inc. v. Iridian Techs., Inc.*, No. 03-cv-04394, 2006 WL 827889, at *2 (D.N.J. Mar 30, 2006).

24.) The sealing of confidential documents and information is an accepted practice in the District of New Jersey. *Gabapentin*, 312 F. Supp. 2d 653, passim.

25.) For all of the above reasons, and because Mylan's interests in the confidential information identified herein outweigh the minimal, if any, public interest in its disclosure, there is good cause to grant Plaintiff's Motion to Seal, as further supplemented by Mylan, the Confidential Documents identified herein.

Dated: May 9, 2013

Respectfully submitted,

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